

11-25-05

FW 1646\$

Attorney's Docket No.: 17083-003002 / 1227B



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Carlos F. Barbas III et al.      Art Unit : 1646  
Serial No. : 09/586,625      Examiner : Joseph F. Murphy  
Filed : June 2, 2000      Cust. No. : 20985  
Conf. No. : 6568  
Title : LIGAND ACTIVATED TRANSCRIPTIONAL REGULATOR PROTEINS

**Mail Stop Amendment**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL LETTER**

Dear Sir:

Transmitted herewith are a Supplemental Information Disclosure Statement, Forms PTO-1449 (3) pages, cited non U.S. patent references, and a check in the amount of \$180.00 for filing in connection with the above-identified application.

☒ The Commissioner is hereby authorized to charge any fees that may be due in connection with this paper or with this application during its entire pendency to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully submitted,

\_\_\_\_\_  
Stephanie Seidman  
Reg. No. 33,779

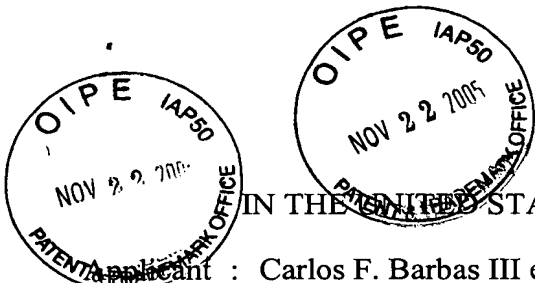
Attorney Docket No. 17083-003002/1227B

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CERTIFICATE OF MAILING BY "EXPRESS MAIL"  
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I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

\_\_\_\_\_  
Stephanie Seidman



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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN  
ACCORDANCE WITH 37 C.F.R. §§ 1.97-1.98**

Because this Supplemental Information Disclosure Statement is filed after the receipt of a First Office Action on the Merits for the above-captioned application, a check for the filing fee of \$180.00 is enclosed. If no proper payment is enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 06-1050.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all references known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Forms PTO-1449 (2 pages) and copies of the cited non U.S. Patent documents are provided herewith.

The documents cited on the Forms PTO-1449 are in the English language. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

The above-captioned application designates three inventors, Carlos F. Barbas, III, Roger Beerli and Michael J. Kadan, and ultimately two assignees, Novartis AG, and The

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Stephanie L. Seidman

Scripps Research Institute. Michael J. Kadan assigned to Novartis AG. Carlos F. Barbas, III and Roger Beerli assigned to The Scripps Research Institute. Thus, the above-captioned application has joint inventors and two assignees.

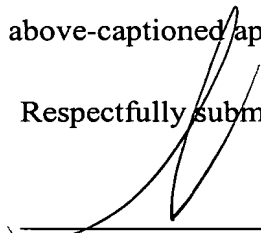
Applicant also makes known to the Examiner the following pending U.S. Applications that have one or more common inventors and/or are commonly owned:

| <u>U.S.S.N.(App. No.)</u> | <u>Filing Date</u> |
|---------------------------|--------------------|
| 10/157,899                | 05/31/02           |
| 10/487,268                | 06/18/04           |
| 10/941,069                | 09/14/04           |
| 10/646,919                | 08/21/03           |

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the references, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

Applicant respectfully requests that the Examiner review the foregoing references and they be made of record in the file history of the above-captioned application:

Respectfully submitted,



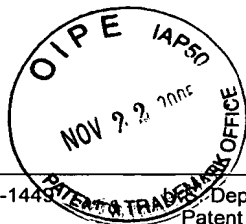
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Sheet 1 of 2

|   |   |   |                               |
|---|---|---|-------------------------------|
| Substitute Form PTO-1449<br>(Modified)<br><br><b>List of Patents and Publications for Applicant's<br/>Information Disclosure Statement</b><br><br>(37 CFR §1.98(b)) | Department of Commerce<br>Patent and Trademark Office | Attorney's Docket No.<br>17083-003002/1227B | Application No.<br>09/586,625 |
|   | Applicant<br>Carlos F. Barbas III et al.              |   |                               |
|   | Filing Date<br>June 2, 2000                           | Group Art Unit<br>1646                      |                               |

| U.S. Patent Documents |           |                 |                  |                    |       |          |                            |
|-----------------------|-----------|-----------------|------------------|--------------------|-------|----------|----------------------------|
| Examiner Initial      | Desig. ID | Document Number | Publication Date | Patentee           | Class | Subclass | Filing Date If Appropriate |
|                       | AA        | 2003/0143559    | 07/31/03         | Sansone, R.P.      | 705   | 1        | 03/27/01                   |
|                       | AB        | 2003/0186841    | 10/02/03         | Barbas III et al.  | 514   | 1        | 04/23/03                   |
|                       | AC        | 2004/0224385    | 04/21/05         | Barbas et al.      | 435   | 69.1     | 06/18/04                   |
|                       | AD        | 2005/0084885    | 04/11/05         | Barbas, III et al. | 435   | 6        | 09/14/04                   |
|                       | AE        | 2005/0148075    | 07/07/05         | Barbas, C.F.       | 435   | 455      | 08/21/03                   |
|                       | AF        | 6,790,941       | 09/14/04         | Barbas III et al.  | 530   | 400      | 02/09/00                   |

| Foreign Patent Documents or Published Foreign Patent Applications |           |                 |                  |                          |       |          |             |    |
|---|-----------|-----------------|------------------|--------------------------|-------|----------|-------------|----|
| Examiner Initial  | Desig. ID | Document Number | Publication Date | Country or Patent Office | Class | Subclass | Translation |    |
|   |           |                 |                  |                          |       |          | Yes         | No |
|   | AG        | 01/52620        | 07/26/01         | PCT                      |       |          |             |    |
|   | AH        | 02/06463        | 01/24/02         | PCT                      |       |          |             |    |
|   | AI        | 2002/097050     | 12/05/02         | PCT                      |       |          |             |    |

| Other Documents (include Author, Title, Date, and Place of Publication) |           |   |
|---|-----------|---|
| Examiner Initial  | Desig. ID | Document  |
|   | AJ        | Alwin et al., "Custom zinc-finger nucleases for use in human cells," Mol. Ther. 12(4): 610-617 (2005)   |
|   | AK        | Beerli, R.R. and C.F. Barbas III, "Engineering polydactyl zinc-finger transcription factors," Nature Biotechnology 20(2): 135-41 (2002)   |
|   | AL        | Blancafort et al., "Designing transcription factor architectures for drug discovery," Mol. Pharmacol. 66(6): 1361-71 (2004)   |
|   | AM        | Blancafort et al., "Genetic reprogramming of tumor cells by zinc finger transcription factors," Proc. Natl. Acad. Sci. USA 102(33): 11716-21 (2005)   |
|   | AN        | Blancafort et al., "Scanning the human genome with combinatorial transcription factor libraries," Nature Biotechnol. 31(3): 269-274 (2003)  |
|   | AO        | Blau et al., "γ-globin gene expression in CID-dependent multi-potential cells established from beta-YAC transgenic mice," J. Biol. Chem. August 30, 2005  |
|   | AP        | Dreier et al., "Development of zinc finger domains for recognition of the 5'-ANN-3' family of DNA sequences and their use in the construction of artificial transcription factors," J. Biol. Chem. 276(31): 29466-78 (2001) |
|   | AQ        | Dreier et al., "Development of zinc finger domains for recognition of the 5'-CNN-3' family DNA sequences and their use in the construction of artificial transcription factors," J. Biol. Chem. 280(42):35588-35597 (2005)  |

|   |                 |
|---|-----------------|
| Examiner Signature  | Date Considered |
| EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |                 |

|  |  |   |                               |
|--|--|---|-------------------------------|
| Substitute Form PTO-1449<br>(Modified)   | U.S. Department of Commerce<br>Patent and Trademark Office | Attorney's Docket No.<br>17083-003002/1227B | Application No.<br>09/586,625 |
| <b>List of Patents and Publications for Applicant's<br/>Information Disclosure Statement</b> |  | Applicant<br>Carlos F. Barbas III et al.    |                               |
|  |  | Filing Date<br>June 2, 2000                 | Group Art Unit<br>1646        |
| (37 CFR §1.98(b))  |  |   |                               |

**Other Documents (include Author, Title, Date, and Place of Publication)**

| Examiner<br>Initial | Desig.<br>ID | Document  |
|---------------------|--------------|---|
|                     | AR           | Graslund et al., "Exploring strategies for the design of artificial transcription factors: targeting sites proximal to known regulatory regions for the induction of $\gamma$ -globin expression and the treatment of sickle cell disease," J. Biol. Chem. 280(5): 3707-14 (2005) |
|                     | AS           | Guan et al., "Heritable endogenous gene regulation in plants with designed polydactyl zinc finger transcription factors," Proc. Natl. Acad. Sci. USA 99(20): 13296-301 (2002)   |
|                     | AT           | Lin et al., "Small-molecule switches for zinc finger transcription factors," J. Am Chem. Soc. 125(3): 612-3 (2003)  |
|                     | AU           | Lund et al., "Promoter-targeted phage display selections with preassembled synthetic zinc finger libraries for endogenous gene regulation," J. Mol. Biol. 340(3): 599-613 (2004)  |
|                     | AV           | Lund et al., "Zinc Finger Transcription Factors Designed for Bispecific Coregulation of ErbB2 and ErbB3 Receptors: Insights into ErbB Receptor Biology," Mol. Cell. Biol. 25(20): 9082-91 (2005)  |
|                     | AW           | Magnenat et al., "In vivo selection of combinatorial libraries and designed affinity maturation of polydactyl zinc finger transcription factors for ICAM-1 provides new insights into gene regulation," J. Mol. Biol. 341(3): 635-49 (2004)                                       |
|                     | AX           | Ordiz et al., "Regulation of transgene expression in plants with polydactyl zinc finger transcription factors," Proc. Natl. Acad. Sci. USA 99(20): 13290-5 (2002)   |
|                     | AY           | Segal et al., "Custom DNA-binding proteins come of age: polydactyl zinc-finger proteins," Curr. Opin. Biotechnol. 12(6): 632-7 (2001)   |
|                     | AZ           | Segal et al., "Evaluation of a modular strategy for the construction of novel polydactyl zinc finger DNA-binding proteins," Biochemistry 42(7): 2137-2148 (2003)  |
|                     | BA           | Segal et al., "Attenuation of HIV-1 replication in primary human cells with a designed zinc finger transcription factor," J. Biol. Chem. 279(15): 14509-19 (2004)   |
|                     | BB           | Segal et al., "Zinc fingers and a green thumb: manipulating gene expression in plants," Curr. Opin. Plant Biol. 6(2): 163-8 (2003)  |
|                     | BC           | Stege et al., "Controlling gene expression in plants using synthetic zinc finger transcription factors," Plant J. 32(6): 1077-86 (2002)   |
|                     | BD           | Tan et al., "Fusion proteins consisting of human immunodeficiency virus type 1 integrase and the designed polydactyl zinc finger protein E2C direct integration of viral DNA into specific sites," J. Virol. 78(3): 1301-13 (2004)  |
|                     | BE           | Xu et al., "A versatile framework for the design of ligand-dependent, transgene-specific transcription factors," Mol. Ther. 3(2): 262-73 (2001)   |

|   |                 |
|---|-----------------|
| Examiner Signature  | Date Considered |
| EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |                 |